Interactive Technologies to Modify Cancer Risk Behaviors

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Abbreviated Abstract

BACKGROUND: Improving cancer risk behaviors, such as physical inactivity, is a national health priority.

METHODS: We conducted a randomized controlled trial to examine the effectiveness of computer-tailored messages, delivered over the Internet, for three common cancer risk behaviors: physical inactivity, inadequate fruit and vegetable consumption, and smoking. Sedentary participants from diverse socio-economic backgrounds were randomized to have access to computer-tailored messages regarding all 3 behaviors, for a period of 12 weeks, or to an alternative treatment, control condition that received weekly printed health education mailings that addressed a variety of health behaviors. The main powered outcome measure was the 7-Day Physical Activity Recall (PAR).

RESULTS: At baseline, the intervention and control condition participants were similar. The average participant age was 45.1 years, 75.3% were female and 82.8% had access to the Internet. Intent to treat analyses showed that, after 3 months, there were no statistically significant between-group differences on physical activity or fruit and vegetable consumption or on physical activity self-efficacy or intent to change physical activity or smoking. Both groups improved significantly from baseline and participants in the intervention condition who used the intervention the most had the greatest gains in physical activity. For example, an intervention condition participant who used the website 12 or more times (at least weekly) increased physical activity by 32 minutes (95% CI 6.4-57.7, p=0.163) and FV intake by 1.44 servings (95% CI 0.73-2.15, p=0.003).

CONCLUSIONS: The computerized, tailored intervention showed no differential effect on cancer risk behaviors across groups. However, both groups improved significantly on physical activity and fruit and vegetable intake and participants in the experimental condition who used the intervention the most had the greatest gains in physical activity. Possible reasons for this lack of a differential effect are hypothesized and may inform the development of future interventions.

Primary Investigator

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As Senior Scientist for The Abacus Group, Dr. Ahern has oversight and responsibility for product research and development for the entire company. Dr. Ahern has had a distinguished career in clinical research and technology transfer initiatives. He possesses over 20 years of R&D expertise in computer applications in medicine and biostatistics. Dr. Ahern has been actively involved in the development of software applications for statistical consulting, integrated voice response technologies, and web-based applications for health care. Dr. Ahern has been awarded as principal investigator or co-investigator over 15 large Federal Government grants and contracts under the Small Business Innovation Research (SBIR) program. He has designed and implemented management information systems for clinical service delivery as well as been the architect of many clinical decision support tools including HeartAge®.

Dr. Ahern received his Ph.D. in clinical psychology from Nova Southeastern University. In addition to his duties at Abacus, Dr. Ahern is the National Program Director of the Health e-Technologies Initiative, a Robert Wood Johnson Foundation® funded program, and is an Assistant Professor of Psychology (Psychiatry) at the Harvard Medical School. Dr. Ahern was previously a member of the professional staff at Massachusetts General Hospital and created the Behavioral Medicine Service. Upon completion of internship training at Brown University Medical School, Dr. Ahern was appointed to the staff of the Miriam Hospital in Providence Rhode Island, on the faculty of Brown University Program in Medicine, and the Director of Research at the Institute of Behavioral Medicine. He has published over 80 original articles; several book chapters, and is a recognized internationally as an expert in eHealth. He serves on multiple advisory boards for RWJF initiatives.

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$1, 00,968.00

Research Objectives

AIM 1: To refine the functional prototype system of tools created in the Phase I to produce a beta version system of tools.

a. Based on a thorough consideration of research, cost, and security issues, we elected to limit the technologies to be tested to an interactive Web-based intervention and tailored print. With review and input from the project officer, it was concluded that the optimal way to proceed was to create a fully functional web-based intervention that accommodated diversity in terms of language, culture, literacy level, gender, and age.
b. The web-based intervention was fully developed (www.myhealthmaximizer.com) using an iterative process based on participatory research and usability testing from a series of focus groups and input from the team of consultants. Research staff input paper-based survey data into the web site in order to produce print tailored feedback for those study participants without computers or computer access to the Internet.

AIM 2: To test the impact of the system of tools on: the diet, physical activity, and smoking patterns of low-income patients in a primary care setting; the quantity and quality of counseling by health care providers to their patients about cancer risk factor modification; and measures of health care utilization.

c. The methodology and findings of the randomized, controlled trial which tests the impact of the three primary outcome variables (diet, physical activity, and smoking patterns) is described in detail below. There was a change in the recruitment strategy and tactics due to logistical concerns related to timely project completion and with careful review and guidance of the project officer. In lieu of recruiting from clusters of physician practices, both consumers and patients were recruited.
d. Since recruitment strategies were amended from strictly recruiting from physician practices, not every participant had an appointment with a primary care provider while participating in the study. Participants were asked at pre-test and post-test whether they had an office visit with their primary care provider and if their providers counseled them on modifying the three cancer risk factor behaviors. Two progress reports were

sent to consenting primary care providers of those participants randomized to the treatment group who provided consent.

e. Health care utilization was measured by the aforementioned procedures regarding office visits.

AIM 3: To assess the degree to which the system of tools was used by patients and providers, and to assess ratings of satisfaction and perceived value by the various stakeholders' (i.e., patients, physicians, and potential purchasers).

f. An iterative process and participatory research approach was used in both Phase I and Phase II. Focus group participants (patients, consumers, physicians, potential purchasers) offered feedback on perceived value and usability for the system of tools.

g. Patients and consumers who participated in the randomized, controlled trial completed satisfaction and perceived value surveys for all study conditions [i.e., website, print from website, control (health brochures)].

AIM 4: To refine and update the preliminary Product Development Plan.
The product development plan was revised and updated at the conclusion of Phase I.

AIM 5: To incorporate the completed product into Abacus Health Solutions suite of products and commence product distribution in Phase III.

The web site is now commercially available as part of the suite of products (www.theabacushealth.com).

Theory/Hypothesis

Primary hypothesis

(i) Participants randomized to the experimental group who receive the interactive, web-based tailored messaging system will significantly increase physical activity at the 13th week post-test when compared to participants in the control condition that receive a non-tailored pamphlet.

(ii) While subjects in the experimental group had unrestricted access to tailored messaging targeting all 3 cancer risk factors (i.e., physical inactivity; smoking; low intake of fruits and vegetables), the primary hypothesis centered around improvements in physical activity. Physical activity was selected because it was likely to be most sensitive to measurable change over the study's limited time period, and because of the widespread prevalence of physical inactivity in the targeted population. Less than one-third of American adults engage in the recommended amounts of physical activity.[1] Forty percent of adults in the United States do not participate in any leisure time physical activity.[1]

Secondary hypotheses

(iii) Participants randomized to the experimental group will demonstrate decreased smoking rates and increased fruit and vegetable intake compared to participants randomized to the control group.

(iv) Participants randomized to the experimental group will demonstrate stages of change progress consistent with a greater readiness to change on one or more of the three behavioral risk factors compared to participants in the control group.

(v) The system of tools will increase the frequency of counseling strategies used by providers to counsel their participants about cancer risk factor modification.

The system of tools will receive high ratings of satisfaction and perceived value by users.

Experimental Design

In order to assess the impact of the system of tools, we conducted a randomized pre-post, control group design study. We delivered the interactive website intervention in the home over a 3-month period to participants recruited via onsite recruitment or flyers at their employment site or health clinic, or through newspaper and online ads.

The user-guided intervention consisted of three components (1) unrestricted access to 6 iterative, tailored message reports, for each of three cancer risk behaviors, physical activity, smoking, and diet, as appropriate, that are tailored to the participant; (2) two reports for the physicians who agree to participate to guide their behavior risk factor counseling; and (3) access to an updated, digital "library" of health information on cancer risk modification by way of Web or print materials sent to the home for patients without Internet access.

Final Sample Size & Study Demographics

The study population was composed of 227 participants (56 adult male and 171 adult female participants). In addition, we sampled a high proportion of Latino participants (14.2%) compared to the Rhode Island population (9.2%). There was also a high proportion of low-income participants [approximately 6% of participants at or below 100% of the federal poverty level; approximately 30% are under the median US income of $42,228]. See Table 1 below for socio-demographics.

To be eligible for the study, participants had to: (1) be over 18 years of age; (2) have a sedentary lifestyle (defined as less than 30 minutes, 3 times per week of moderate-intensity physical activity); (3) speak English or Spanish as the primary language spoken at home at an 8th grade literacy level; (4) agree to participate in the pre-and post test data collection, and not to move out of the area within 3 months of enrollment in the study, and (5) for those potential participants who have a positive result on the PARQ3 (a physical activity screening measure for areas that may potentially preclude the adoption of physical activity), provide consent for the researchers to obtain approval from their physician to participate in the study and potentially increase their level of physical activity. Note, however, that

participants did not have to agree to modify risk factors at study onset, therefore, participants not ready to change any of the behaviors were not excluded from the study. Individuals were excluded from participation if they were currently in a formal exercise program in which they regularly exercise 90 minutes or more per week, using smokeless tobacco, nicotine replacement therapy, or other smoking cessation treatment, or were currently undergoing active diagnostics or treatment for a cancer or a similar disorder, or do not have physician approval to participate because of identified risk factors related to the increase in physical activity.

Potential study participants were recruited via onsite recruitment or flyers at their employment site or health clinic, or through newspaper and online ads.

Data Collection Methods

Setting

The study was implemented in participants' homes. Participants with Internet access at home received the web-based intervention and those without Internet access received mailings to the home of website content. Control group participants received mailings of the National Institute of Health brochures at their home.

The schedule and contents of the two assessments were as follows. The baseline assessment (BL) occurred at the beginning of Month 1 of the participant's enrollment period. This baseline assessment included a comprehensive battery of outcome measures (see list below). Three months after completion of the baseline assessment, each study participant was prompted to complete the 13th week post assessment battery (Post). This post assessment included the same comprehensive battery of measures administered at baseline.

Screening Measures

Physical activity level: Physical activity level was screened according to inclusion criteria (less than 90 minutes of moderate-intensity physical activity per week).

Physical Activity Readiness Questionnaire (PARQ). This 7-item screening tool assesses for any potential health factors that may preclude adoption of physical activity and warrants further medical screening to this end. Positive PAR-Q resulted in seeking active consent from Primary Care Provider for individual to participate in the study.

Outcome Measures

Primary Outcome Measure:

Physical activity

Seven Day Physical Activity Recall (PAR). The PAR is a valid and reliable interviewer-administered procedure that was originally developed for the Stanford Five City Project. The PAR is also sensitive to change in physical activity intervention studies. It is the main physical activity measurement for four other projects in which Dr. Marcus (co-investigator) is involved (Project Active, ACT, Project PRIME, and Commit to Quit).

Secondary Outcome Measures:

Physical activity

Exercise Self-Efficacy, Decision Making, and Stages and Processes of Change. We measured exercise-specific self-efficacy with the measure developed by Marcus and colleagues. Decision-making for exercise was measured by the Decisional Balance instrument and both Stages and Processes of Change for exercise behavior was measured by instruments developed by Marcus and colleagues. For the Stages of Change instrument the Kappa index of reliability over a 2-week period was 0.789. Concurrent validity for this measure is demonstrated by its significant association with the 7-day Physical Activity Recall (PAR) questionnaire. The 5-item self-efficacy measure has an internal consistency of 0.76 and test-retest reliability over a 2-week period of 0.909. Internal consistency for the decisional balance measure is 0.79 for the Pros scale and 0.95 for the Cons scale10. Internal consistency for the Processes of Change scales average 0.83.

Diet

Fruit and Vegetable Intake. Our quantitative measure of changes in dietary intake and food habits was a 10-item assessment tool to measure intake of fruits and vegetables, The All-Day Screener. This tool has been used widely to track changes in fruit and vegetable intake in specific population groups. The "all-day" instrument includes 12 foods. Portion size questions are asked. The advantages were that it (1) reflects usual dietary intake, (2) does not affect participants' habitual eating patterns, (3) allows individuals to be ranked or classified by food intake, (4) does not require time-consuming data coding and entry, (5) reflects the intake of nutrients of interest in our intervention program, i.e. fruits and vegetables, etc. , (6) asks probing behavioral questions, which enables us to better measure changes in types of food or food preparation that are targeted during intervention, and (7) includes summary

questions that enable better quantification of fruit and vegetable intake. To aid in portion size quantification we will use small, medium, and large portion size photographs like those used by WHO if they prove more acceptable to this population.

Smoking

Smoking Status. This was assessed at baseline and at the 13th week post-test using one question to determine if a participant continues to smoke or has quit smoking.

Motivation to Quit Smoking. Motivation was assessed at baseline and at the 13th week post-test using the Contemplation Ladder. Although the Stages of Change algorithm has been a widely used measure of readiness to change behavior, some investigators recently have expressed concern over the adequacy of discrete stages as assessments of motivation and the use of such stages as diagnostic tools to match subjects to treatment , . Given this controversy, we will use both the Stages of Change algorithm and the Contemplation Ladder, 17 to measure motivation to quit smoking.

Saliva Cotinine Test: Self-reported abstinence of at least 7 consecutive days was verified with saliva cotinine test. Cotinine is a major metabolite of nicotine. Cotinine levels could be elevated in patients who use nicotine replacement products or are exposed to secondhand smoke. Therefore, we assessed whether participant cotinine levels are influenced by these two conditions. Studies comparing non-smokers and smokers have consistently found that measurement of cotinine in the urine, saliva, or serum can distinguish active smokers from non-smokers. Active smokers almost always have saliva levels higher than 15 ng/ml and sometimes greater than 500 ng/ml.22 Results were analyzed by Salimetrics, Inc. and a cutoff of 100 ng/ml was used to distinguish a smoker from a non-smoker.

Provider Counseling Participant Survey. One aim of the study is to gain a preliminary understanding of the impact of the tailored feedback on provider counseling for the adoption of one or more of the three targeted health behaviors. For those participants and primary care providers who both consented to have the primary care provider receive written reports on participant interest in modifying one or more of the targeted health behaviors, we surveyed participants at baseline and post-treatment to determine if their primary care physician counseled them on modifying these health behaviors. Pre- and post-surveys will contain a list of yes/no questions such as “Did your doctor counsel you on quitting smoking?” Scoring will be accomplished via a count of counseling strategies endorsed by the participant as used by their physician during their medical visit.

Evaluation Methods Barriers & Solutions

The following 6 outcomes were analyzed: PAR, Self Efficacy, Decisional Balance (DB), FV Intake, FV ladder, SMK ladder. Change sores from baseline to the end of the 12-week intervention period were used as the dependent variable. To accommodate the possible dependence of the change scores on baseline values of the outcome and to account for differential treatment effects by gender, the following three regression models were fit in a hierarchical fashion with binary indicators for Treatment and Gender and baseline values of the outcome standardized to zero mean and unit scale:

2. (Baseline + Gender) * Treatment
3. Baseline * Treatment
4. Baseline + Treatment

Research Results

Major Findings

As can be seen in Table 1, Randomization was successful at the overall sample level, with only Household Size differing significantly between groups. Print households tended to be slightly larger than those in the Web group (Print=2.90, Web=2.71, p=.043). The subset of smokers shows imbalances in 3 additional covariates: age, cigarettes per day, mental health.

Table 1: Socio-demographic characteristics of sample at baseline

	Overall n=227		**Print group n=103**		**Web group n=124**		
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	***p***
Age	45.11	12.02	44.21	12.78	45.85	11.34	0.31
Years of education	15.29	3.12	15.46	3.03	15.15	3.20	0.46
	n	**%**	**n**	**%**	**n**	**%**	
Sex (Female)	171	75.33	76	73.79	95	76.61	0.74
Race (Caucasian)	169	74.45	79	76.70	90	72.58	0.99
Hispanics	33	14.54	14	13.59	19	15.32	0.86
Income							0.92
<30k	69	30.53	30	29.13	39	31.71	
30k-50k	47	20.80	22	21.36	25	20.33	
50k-70k	44	19.47	19	18.45	25	20.33	
70k+	66	29.20	32	31.07	34	27.64	
Insurance (Yes)	204	89.87	93	90.29	111	89.52	0.83

PCP (Yes)	201	88.55	87	84.47	114	91.94	0.12
Net access (Yes)	188	82.82	88	85.44	100	80.65	0.44
Email Availability (Yes)	179	78.85	82	79.61	97	78.23	0.93

No significant Gender by Treatment interactions or Gender main effects were detected for any of the outcomes of interest. Similarly, none of the Treatment effects appeared to depend on baseline levels of the outcome, even after Gender was dropped from the model. Therefore, the findings can be summarized in terms of model (3), in which the intercept corresponds to the mean change in the reference group for a subject with average value of the outcome at baseline, whereas the Tx slope corresponds to the mean difference in changescores between the Web and Print arms of the intervention for such a "typical" subject. By coding the Tx indicator first as Web=1, Print=0 and then as Web=0, Print=1, we were able to extract from the intercepts the mean residualized changescores for each intervention arm in turn. The findings are summarized in Table 2.

Table 2: Group differences in residualized changescores

	Web group n=124			**Print group n=103**			**Web-Print**		
Primary Outcomes	**Mean**	**SE**	***p***	**Mean**	**SE**	***p***	**Mean**	**SE**	***p***
PAR Minutes	110.80	12.36	0.00	91.45	13.56	0.00	19.35	18.36	0.29
Self Efficacy	0.21	0.06	0.00	0.22	0.06	0.00	-0.01	0.09	0.90
Decisional Balance	0.10	0.07	0.14	0.08	0.08	0.32	0.03	0.11	0.81
F&V intake	1.67	0.43	0.00	1.29	0.48	0.01	0.38	0.64	0.56
F&V ladder	0.12	0.13	0.35	0.48	0.15	0.00	-0.36	0.20	0.07
SMK ladder	0.54	0.40	0.18	0.90	0.41	0.03	-0.35	0.57	0.54

Although the average change experienced by a "typical" control subject was statistically significant for PAR minutes of exercise, Self Efficacy and F&V intake on both the Web and Print groups, the between-group differences in changescores were not. As seen from Table 2, the only outcome for which the Treatment effect approached statistical significance (F&V ladder, p=.07), was in the opposite direction to the hypothesis for that outcome, with the average changescores in the Print group exceeding those in the Web group.

Successive log-ins from treatment group participants yielded incremental gains in physical activity (p=.0163) and F&V intake (p=.0003). In particular, a Web-group participant which completed the 12 logins required by study protocol, experienced increases in physical activity of 32 minutes (95% CI 6.40-57.68) and in F&V intake of 1.08 servings (95% CI 0.73-2.15).

Barriers & Solutions

These findings must be understood in the context of several limitations. First, the study included volunteers drawn from three separate populations (newspapers, worksites, and primary care practices), so generalizing the findings to any one population is difficult and sub-samples are too small to make sub-analyses informative. It should also be noted that the study sample had a lower household income than the average Internet users, as Internet access and use correlations closely with financial resources. If this intervention was made available to, for example, members of a health plan, we anticipate that it would be made available as an Internet-only intervention and that the users would likely be different than in this study. Nearly 20% of our participants did not have Internet access at all and would therefore not be able to use the intervention. With that said, our study included a relatively large percentage of lower income and ethnic minority participants compared to other studies of web-based physical activity interventions. For example, 91% of participants in the study by Napolitano and colleagues were Caucasian, compared to 75% in the current study. In addition, our study included a higher percentage of Latino participants (14.2%) compared to the Rhode Island population (9.2%) observed in the 2000 census.

In summary, these findings illustrate the challenge in demonstrating the utility and impact of technology-based, multiple risk factor reduction programs. Although there were clear benefits to participants who actually used the functions on the website, the improvements observed were not superior to the improvements reported by participants who were mailed content-relevant, print materials. Even though the website did not prove superior to print content in terms of outcomes, it is arguable that a website is more scalable and would likely incur less incremental costs compared to mailing of print materials and that increasing use of the website (e.g., dose) may lead to improved outcomes (e.g., effect). Future research is warranted in order to determine the benefits and potential cost benefits of technology-based programs for multiple risk factor reduction.

Product(s) Developed from This Research

MyHealthMaximizer® offers evidence-based, tailored feedback and self-monitoring tools that are useful, reliable, and up-to-date static health information that is written at a low literacy level and translated into Spanish. MyHealthMaximizer® addresses nutrition, physical activity, and smoking cessation issues in an effort to reduce the risk of cancer and other chronic medical conditions.

The commercial sale and delivery of the web tool has been bundled with other Abacus developed evidence-based consumer support web tools to support broader and customized interventions for employer groups.

To help employers and their employees navigate the healthcare system and get to what's really important —feeling good, and doing it economically— Abacus Health Solutions delivers the healthcare industry's most unique and beneficial programs and services.

- Trying to contain costs while ensuring the highest quality care
- Combating overload from the mountain of medical and healthcare management information that's available
- Having real-time data that allows cost-saving interventions to be made
- Keeping up to date with managed care rules and self-management skills

Abacus Health Solutions delivers the tools to address these challenges in the form of interactive, user-friendly online information and applications, supplemented by personalized phone support. Using our proprietary and empirically proven methodologies, these unique and powerful tools allow users to identify their health-related goals, get intelligent and automatic feedback, and receive actionable direction. The power to immediately make a positive impact on their health and healthcare programs is placed firmly in their hands.

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[i] Surgeon General, US Department of Health and Human Services, www.surgeongeneral.gov/topics/obesity/calltoaction/fast_glance.htm